Filovirus Animal Model Workshop

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September 11, 2007

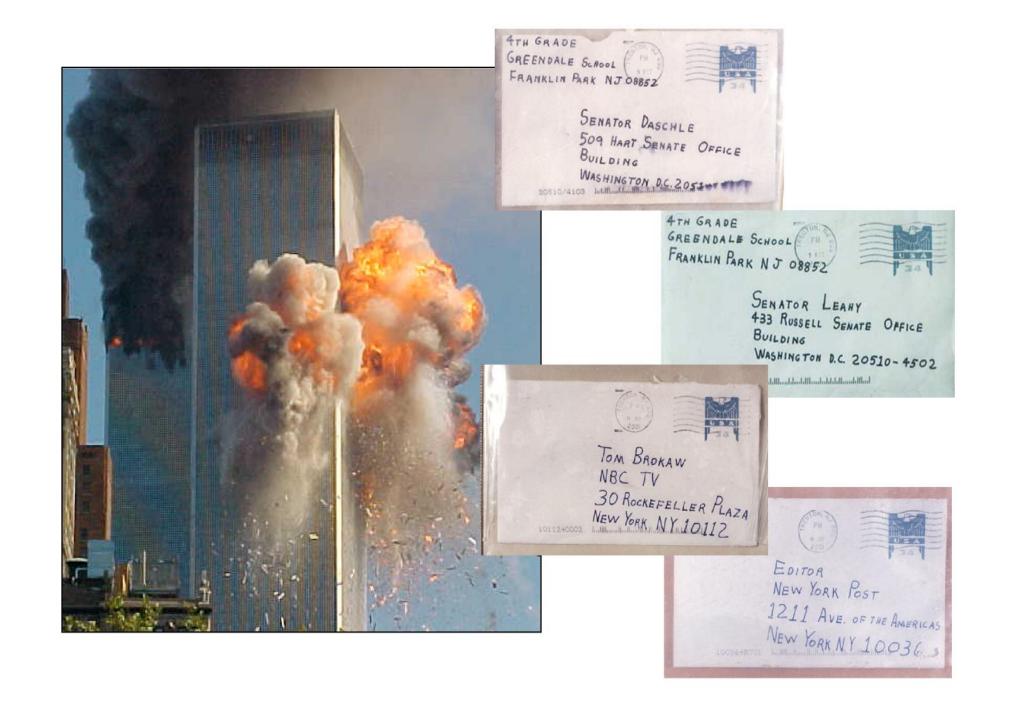
DEPARTMENT OF HEALTH OF HEALTH



A Premature Declaration of Victory Over Infectious Diseases

"We can look forward with confidence to a considerable degree of freedom from infectious diseases at a time not too far in the future. Indeed... it seems reasonable to anticipate that within some measurable time... all the major infections will have disappeared."

- Aidan Cockburn, *The Evolution and Eradication of Infectious Diseases*, 1963.



SARS: A New Challenge to Global Health



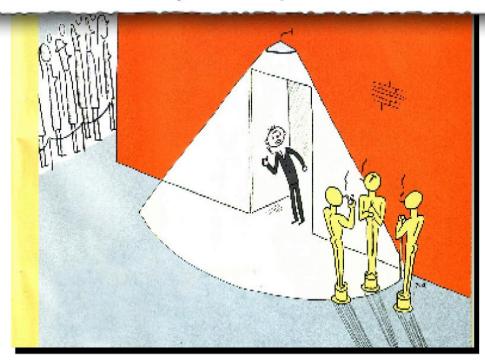


A Reporter at Large

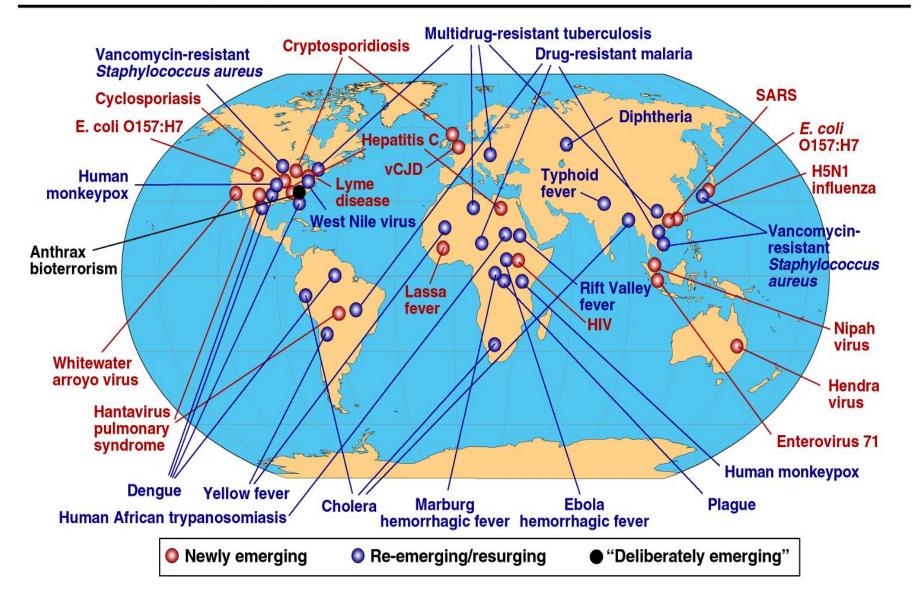
NATURE'S BIOTERRORIST

Is there any way to prevent a deadly avian-flu pandemic?

By Michael Specter



Global Examples of Emerging and Re-Emerging Infectious Diseases





Federal Register Vol. 72, No. 53 Tuesday, March 20, 2007

HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

Strategy for Chemical, Biological, Radiological and Nuclear Threats



HHS PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURE ENTERPRISE

IMPLEMENTATION PLAN

FOR CHEMICAL, BIOLOGICAL,
RADIOLOGICAL AND NUCLEAR THREATS





U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF THE ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
OFFICE OF PUBLIC HEALTH EMERGENCY MEDICAL COUNTERMEASURES

APRIL 2007

'Animal Rule'

- Human efficacy evaluation not technically possible or ethically feasible
- Human clinical data still needed
 - Immunogenecity / PK data
 - Safety demonstration
- Approval comes with post-marketing studies and use restrictions
- Requires appropriate animal efficacy data

Integrated R&D for Product Development

NIH Activities

HHS Activities

BARDA

BioShield/Flu

Acquisition

Basic Applied Product Development

Early → Advanced → End-Stage

Early→Advanced

□Pilot lot production

□Preclinical studies

□ Animal efficacy models

□Phase I/II clinical trials

Applied

□Fundamental

Science

Basic

■Target identification

□Screening

□ Animal model development

End-Stage

□Commercial scale development

□EUA-enabling studies

□ Large scale safety trials

□ 'Animal rule' efficacy studies

□ Regulatory filing activities

